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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/485,845      | 04/26/2000  | HIDENORI FUNAMIZU    | 2554-7              | 5849             |

23117 7590 05/10/2004

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EXAMINER

COLEMAN, BRENDA LIBBY

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1624

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                               |                                 |  |
|------------------------|-------------------------------|---------------------------------|--|
| <b>Advisory Action</b> | Application No.<br>09/485,845 | Applicant(s)<br>FUNAMIZU ET AL. |  |
|                        | Examiner<br>Brenda Coleman    | Art Unit<br>1624                |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 12 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): see attached Advisory Action.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 67.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 68-76 and 85.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

### **ADVISORY ACTION**

Claims 67-76 AND 85 are pending in the application.

The period for reply continues to run THREE MONTHS from the date of the final rejection. Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a) accompanied by the appropriate fee. The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. A reply within the meaning of 37 CFR 1.113 or a request for a continued examination (RCE) in compliance with 37 CFR 1.114 must be timely filed to avoid abandonment of this application.

The amendment filed February 12, 2004 under 37 CFR 1.116 in reply to the final rejection has been entered, but is not deemed to place the application in condition for allowance. For purposes of appeal, the status of the claims is as follows:

Allowed claim(s): 67

Rejected claim(s): 68-76 and 85

Claim(s) objected to: NONE

This action is in response to applicant's amendment dated February 12, 2004.

Claims 67 and 69 have been amended.

### ***Response to Arguments***

Applicant's arguments filed February 12, 2004 have been fully considered with the following effect:

1. The applicants' amendments and arguments are sufficient to overcome the improper Markush rejection of claim 67, labeled paragraph 1 in the last office, which is hereby **withdrawn**.
2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claim 69, labeled paragraph 3 in the last office, which is hereby **withdrawn**.
3. With regards to the 35 USC § 112, first paragraph rejection labeled paragraph 4 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated that when one considers all of the information in the as-filed specification it will be apparent that the inventors did indeed contemplate a series of compounds and homologues which include the structures. While it is noted that example 68 and 172 are two species claimed in claim 67 which is indicated as being allowable with this action. The ring structure of example 68, i.e. 1,4-dioxo-2,3-dihydro-benzo[1,5]thiazepine and the definition of D of example 172, i.e. -NH-CH<sub>2</sub>-CH(OH)-CH<sub>2</sub>-NH-CH<sub>2</sub>-CH(OH)-CH<sub>3</sub> is not explicitly defined in the specification with respect to the variables A<sub>1</sub> and D. The specification does not include either one of these definitions in the preferred embodiments spanning pages 11-15 where the ring systems the applicants have contemplated for A<sub>1</sub> and the amines for D are defined. The definition of A<sub>1</sub> where A<sub>1</sub> is 1,4-dioxo-2,3-dihydro-benzo[1,5]thiazepine in examples 67 and 68 is part of two single species with specific variables, not the description of the genus or a preferred embodiment of formula I. The definition of D where D is -NH-CH<sub>2</sub>-

CH(OH)-CH<sub>2</sub>-NH-CH<sub>2</sub>-CH(OH)-CH<sub>3</sub> in example 172 is part of a single species with specific variables, not the description of the genus or a preferred embodiment of formula

I. Additionally, recent case law *Tronzo v. Biomet* 47 USPQ2d 1829 states that a species in a prior application does not provide written description to a generic claim.

Claims 68-76 and 85 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record and stated above.

***Allowable Subject Matter***

4. Claim 67 is allowed. None of the prior art of record nor a search in the pertinent art area teaches the compounds as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman  
Primary Examiner Art Unit 1624  
April 12, 2004